REMARKS

Claims 1-22 are pending in the present application with claims 1-18 withdrawn from consideration. Accordingly, claims 19-22 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

According to the Office Action summary included with the Office communication dated January 22, 2008, this action has been made final. However, according to MPEP 706.07(a), a final rejection upon second action is not proper where the Examiner introduces a new ground of rejection that is neither necessitated by Applicants' amendment of the claims nor based on information submitted in an IDS filed during the period set forth in 37 CFR 1.97(c). Applicants believe this to be the case in view of Examiner's language that "upon further consideration, a new ground of rejection has been made." As such, Applicants aver that this Office Action cannot stand for a final rejection.

Claims 19-22 have been rejected under 35 U.S.C. §103(a) as obvious over McMahon *et al.* (US 6,004,967) in view of Lee *et al.* (US2003/0230488 A1) as evidenced by www.wikipedia.com.

The McMahon reference discloses a pharmaceutical compound, A1, and describes its solubility in several excipients. The Examiner cites Table 4 which lists the excipients used for solubility testing of A1. However, the McMahon reference does not teach a high-throughput method for screening large numbers of formulations. In addition, the Examiner has conceded that McMahon does not disclose either the dispensing of less than 250 microliters of an excipient or the use of a positive displacement pump. Furthermore, there is no sample array disclosed in McMahon.

The McMahon reference describes methods and compositions for treating skin disorders with a quinazoline derivative. The Examiner has failed to point to any part of the reference that teaches or suggests the high-throughput screening of liquid formulations. In fact, the only cited portions of the reference that indicate solubility testing at all (lines 29-34 of column 17, and Table 4 of column 20) expressly describe such testing with respect to a single compound, A1. In contrast, the present invention is useful for a large number of compounds and does not rely on low-throughput, previously

known methods of excipient solubility testing. In conclusion, the McMahon reference provides no teaching or suggestion of high-throughput liquid formulation screening for a large number of compounds, but only describes the dissolution of a single compound, A1, in a handful of excipients to determine their inherent solubilities.

The Lee reference discloses the preparation of microfluidic devices for the application of rapid electrophoretic separation. The Examiner cites language describing solubility screens in paragraph [0005] and also cites the apparatus described, which includes a microplate and a positive displacement pump. However, like the McMahon reference, the Lee reference does not describe a high-throughput method for screening large numbers of formulations. The Examiner's characterization of Lee, that it "disclose[s] an apparatus for conducting solubility tests", is misleading. The word "solubility" is mentioned only once in the entire document and even then only in the background section where the author is attempting to put the invention in the greater context of microfluidic devices. Nowhere does Lee describe, either expressly or inherently, that his invention can be used for solubility screening. Instead, Lee describes the invention as methods and systems for the electrophoretic separation of samples. The Lee reference provides no teaching or suggestion of high-throughput liquid formulation screening for a large number of compounds, but only describes systems and methods for high-throughput electrophoretic separation.

Obviousness requires a teaching that all elements of the claimed invention are found in the prior art and "a reason that would have prompted a person or ordinary skill in the relevant field to combine the elements in the way the claimed new invention does" *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741, 82 USPQ2d 1385, 1396 (2007). While the combination of the McMahon and Lee references may include the elements described in pending claim 19, the Examiner has not provided a reason that would have prompted one of ordinary skill in the art to combine a reference teaching the dissolution of a single compound, A1, in a handful of excipients with another reference describing systems and methods for high-throughput electrophoretic separation to arrive at the claimed invention. Neither reference discusses the screening of a large number of compounds and liquid formulations. As such, the Examiner has not met his burden of

establishing *prima facie* obviousness. MPEP 2143. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Respectfully submitted,

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